PRESS RELEASE

3 September 2021

Nature Medicine publishes phase 3 anakinra study results in patients with COVID-19 pneumonia

Swedish Orphan Biovitrum AB (publ) (Sobi™) (STO:SOBI) and the Hellenic Institute for the Study of Sepsis today announce that *Nature Medicine* has published positive results from the investigator-sponsored phase 3 SAVE-MORE study evaluating anakinra plus standard of care (SOC) in patients with moderate-to-severe COVID-19 pneumonia. The study demonstrated that early and targeted use of anakinra, in addition to current SOC, reduces risk of death, reduces ICU admission and increases likelihood of full recovery in hospitalised COVID-19 patients with poor prognosis due to risk of severe respiratory failure (SRF).

KEY HIGHLIGHTS

- Early treatment with anakinra showed considerable efficacy and reduced risk of disease progression and death by 64 percent, according to day 28 results from the SAVE-MORE study.
- Relative decrease of mortality was 55%, reaching 80% for patients with cytokine storm.
- Proportion of patients who fully recovered exceeded 50 percent, and number of patients remaining with severe disease reduced by 54 percent. Average time until hospital and intensive care unit (ICU) discharge was reduced by one and four days.

The SAVE-MORE study, conducted by the Hellenic Institute for the Study of Sepsis, is the first large, pivotal randomised controlled trial to specifically evaluate a patient population at risk of progressing to critical state and demonstrate considerable benefit of earlier intervention for the prevention of disease progression and death. Co-administered treatments were similar between the two arms of the study and included dexamethasone, anticoagulants and remdesivir. The study results were previously reported in May.

“The results published in *Nature Medicine* provide the only data available on prevention from early stage progressing to critical status, indicating that the inflammatory disease needs to be treated earlier with a specifically targeted approach to IL-1 alpha and IL-1β,” said lead investigator Evangelos J. Giamarellos-Bourboulis, Professor of Internal Medicine and Infectious Diseases, National and Kapodistrian University of Athens, President of the European Shock Society, and Chairman of the European Sepsis Alliance.

"Publication of the SAVE-MORE study results in *Nature Medicine* demonstrates the significance of these data and further advances our understanding of the role of IL-1 in COVID-19,” says Guido Oelkers, CEO of Sobi. “We hope to contribute to an improvement of care for patients during this critical time and welcome the opportunity to work closely with the EMA and other regulatory agencies regarding these results."

About SAVE-MORE
SAVE-MORE (NCT04680949); suPAR-Guided Anakinra Treatment for Management of Severe Respiratory Failure by COVID-19) is a large, pivotal, confirmatory, phase III randomized controlled trial (RCT) in over 600 hospitalised patients. The trial aims to evaluate the efficacy and safety of early start of anakinra guided by suPAR in patients with LRTI by SARS-CoV-2 in improving the clinical state of COVID-19 over 28 days, as measured by the ordinal scale of the 11-point World Health Organization (WHO) clinical progression scale (CPS). Anakinra was administered at a dose of 100mg/day SC for up to 10 days. Of 1,060 patients screened, 606 patients were randomised 2:1 across 37 sites in Greece and Italy. SAVE-MORE is an investigator-sponsored study conducted independently by Professor Giamarellos-Bourboulis, with the Hellenic Institute for the Study of Sepsis being the sponsor. Sobi has supported the study with study drug and funding.

About Kineret® (anakinra)
Kineret® is an interleukin-1 α and β receptor antagonist that is indicated in the US for reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis, in patients 18 years of age or older who have failed one or more disease modifying antirheumatic drugs (DMARDs), for the treatment of neonatal-onset multisystem inflammatory disease (NOMID, a form of cryopyrin-associated periodic syndromes (CAPS)), and for the treatment of Deficiency of Interleukin-1 Receptor Antagonist (DIRA).
In Europe, Kineret is indicated in adults for the treatment of the signs and symptoms of rheumatoid arthritis (RA) in combination with methotrexate, with an inadequate response to methotrexate alone. In addition, Kineret is indicated in adults, adolescents, children and infants aged 8 months and older with a body weight of 10 kg or above for the treatment of cryopyrin-associated periodic syndromes (CAPS), including - neonatal-onset multisystem inflammatory disease (NOMID)/chronic infantile neurological, cutaneous, and articular syndrome (CINCA), Muckle-Wells syndrome (MWS) and familial cold auto inflammatory syndrome (FCAS). Kineret is indicated for the treatment of Familial Mediterranean fever (FMF). Kineret should be given in combination with colchicine, if appropriate. It is also indicated in adults, adolescents, children and infants aged 8 months and older with a body weight of 10 kg or above for the treatment of Still's disease, including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still's Disease (AOSD), with active systemic features of moderate to high disease activity, or in patients with continued disease activity after treatment with non-steroidal anti-inflammatory drugs (NSAIDs) or glucocorticoids. Kineret can be given as monotherapy or in combination with other anti-inflammatory drugs and disease-modifying antirheumatic drugs (DMARDs).

For full US prescribing information visit www.kineretrx.com and for full European prescribing information visit the EMA website. Anakinra has not been approved for the treatment of COVID -19.

About suPAR and suPARnostic®
suPAR (soluble urokinase plasminogen activator receptor) is the biomarker detected by ViroGates' suPARnostic® products and is a protein in plasma, measurable in every human being. suPAR is considered a general risk status biomarker indicating disease presence, disease severity and progression, organ damage and mortality risk across disease areas such as cardiovascular diseases, kidney diseases, type 2 diabetes, cancer, etc.

About the Hellenic Institute for the Study of Sepsis
The Hellenic Institute for the Study of Sepsis (HISS) is a non-profit organisation situated in Athens. HISS coordinates the research activities in sepsis and severe inflammatory disorders since 2010 of 58 departments of Internal Medicine and Intensive Care Units in Greece and abroad. HISS has sponsored the conduct of more than 30 clinical studies and has a track record of providing support for more than 100 publications. The phase II SAVE trial and the phase III SAVE-MORE trial were sponsored by HISS. For more details visit www.sepsis.gr
Contact details: Evangelos J. Giamarellos-Bourboulis egiamarel@med.uoa.gr; Leda Efstratiou insepsis@otenet.gr

About Sobi
Sobi is a specialised international biopharmaceutical company transforming the lives of people with rare diseases. Sobi is providing sustainable access to innovative therapies in the areas of haematology, immunology and specialty indications. Today, Sobi employs approximately 1,500 people across Europe, North America, Middle East, and Asia. In 2020, Sobi's revenue amounted to SEK 15.3 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. You can find more information about Sobi at www.sobi.com**.**

For more information, please contact
Paula Treutiger, Global Head of Communication
+46 733 666 599
paula.treutiger@sobi.com

Maria Kruse, Corporate Communication & Investor Relations
+46 767 248 830
maria.kruse@sobi.com